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EXAMINER	
HUYNH, PHUONG N	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,645	ANKER ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *One* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43,45-63,65-70,72,74 and 76-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-43, 45, 46-63, 65-70, 72, 74, and 76-81* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

I. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.

II. Claims 1-43, 45, 46-63, 65-70, 72, 74, and 76-81 are pending.

Election/Restrictions

III. Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372:

1. Claims 2-6, 8-10, 17-18, 21-23, 25-27, 45, 54-58, and 69-74, drawn to a method of treating, preventing or ameliorating chronic heart failure or acute heart failure comprising administering **bile acid** that is able to reduce the production, absorption and/or the effect of an endotoxin (LPS).

2. Claims 2-4, 7-10, 17-18, 21-23, 25-27, 45, 54-56, 59, and 69-74, drawn to a method of treating, preventing or ameliorating chronic heart failure or acute heart failure comprising administering a **LPS binding protein** that is able to reduce the production, absorption and/or the effect of an endotoxin (LPS).

3. Claims 2-4, 7-10, 12-18, 20-23, 25-27, 45, 4-56, 60, and 69-74, drawn to a method of treating, preventing or ameliorating chronic heart failure or acute heart failure comprising administering a **bactericidal/permeability increasing protein** that is able to reduce the production, absorption and/or the effect of an endotoxin (LPS).

4. Claims 2-4, 7-10, 17-18, 20-23, 25-27, 45, 54-56, 61, 69-74, and 80 drawn to a method of treating, preventing or ameliorating chronic heart failure or acute heart failure comprising administering a **lipoprotein** or lipoprotein mixture that is able to reduce the production, absorption and/or the effect of an endotoxin (LPS).

5. Claims 2-4, 7-10, 17-23, 25-27, 45, 54-56, 63, and 69-74, drawn to a method of treating, preventing or ameliorating chronic heart failure or acute heart failure comprising administering an **antibody capable of binding to endotoxin (LPS)** that is able to reduce the production, absorption and/or the effect of an endotoxin (LPS).

6. Claims 2-4, 8-11, 17-18, 20-23, 25-27, and 45, drawn to a method of treating, preventing or ameliorating chronic heart failure or acute heart failure comprising administering **activated charcoal activated carbon** that is able to reduce the production, absorption and/or the effect of an endotoxin (LPS).

7. Claims 2-4, 8-11, 17-18, 20-23, 25-27, and 45, drawn to a method of treating, preventing or ameliorating chronic heart failure or acute heart failure comprising administering **Fuller's earth** that is able to reduce the production, absorption and/or the effect of an endotoxin (LPS).

8. Claims 2-4, 8-11, 17-18, 20-23, 25-27, and 45, drawn to a method of treating, preventing or ameliorating chronic heart failure or acute heart failure comprising administering **attapulgite** that is able to reduce the production, absorption and/or the effect of an endotoxin (LPS).

9. Claims 2-4, 8-11, 17-18, 20-23, 25-27, and 45, drawn to a method of treating, preventing or ameliorating chronic heart failure or acute heart failure comprising administering **Kaolin** that is able to reduce the production, absorption and/or the effect of an endotoxin (LPS).

10. Claims 2-4, 8-11, 17-18, 20-23, 25-27, and 45, drawn to a method of treating, preventing or ameliorating chronic heart failure or acute heart failure comprising administering **bentonite** that is able to reduce the production, absorption and/or the effect of an endotoxin (LPS).

11. Claims 2-4, 8-11, 17-18, 20-23, 25-27, and 45, drawn to a method of treating, preventing or ameliorating chronic heart failure or acute heart failure comprising administering **clay** that is able to reduce the production, absorption and/or the effect of an endotoxin (LPS).

12. Claims 2-4, 8-11, 17-18, 20-23, 25-27, and 45, drawn to a method of treating, preventing or ameliorating chronic heart failure or acute heart failure comprising administering **colostrum** that is able to reduce the production, absorption and/or the effect of an endotoxin (LPS).

13. Claims 2-4, 17-23, 25-27, 45, 54-56, 65, 69-74, and 76-77, drawn to a method of treating, preventing or ameliorating chronic heart failure or acute heart failure comprising administering an **antibody that is able to bind the CD14 receptor** that is able to reduce the production, absorption and/or the effect of an endotoxin (LPS).

14. Claims 2-4, 17-23, 25-27, 45, 54-56, 66, 69-74, and 76-77, drawn to a method of treating, preventing or ameliorating chronic heart failure or acute heart failure comprising administering a **soluble CD14 receptor** that is able to reduce the production, absorption and/or the effect of an endotoxin (LPS).

15. Claims 2-4, 17-23, 25-27, 45, 54-56, 67, 69-74, 76-77, and 81, drawn to a method of treating, preventing or ameliorating chronic heart failure or acute heart failure comprising administering a **non-functional agonist of a toll-like receptor** that is able to reduce the production, absorption and/or the effect of an endotoxin (LPS).

16. Claims 2-4, 17-18, 21-27, and 45, drawn to a method of treating, preventing or ameliorating chronic **heart failure** or acute heart failure comprising administering **IGF-1**, that is able to reduce the production, absorption and/or the effect of an endotoxin (LPS).

17. Claims 2-4, 17-18, 21-27, and 45, drawn to a method of treating, preventing or ameliorating chronic heart failure or acute heart failure comprising administering **allopurinol**, that is able to reduce the production, absorption and/or the effect of an endotoxin (LPS).

18. Claims 2-4, 17-18, 21-27, and 45, drawn to a method of treating, preventing or ameliorating chronic heart failure or acute heart failure comprising administering **oxipurinol**, that is able to reduce the production, absorption and/or the effect of an endotoxin (LPS).

19. Claims 2-4, 17-18, 21-27, and 45, drawn to a method of treating, preventing or ameliorating chronic heart failure or acute heart failure comprising administering unspecific or specific **xanthine oxidase inhibitor**, that is able to reduce the production, absorption and/or the effect of an endotoxin (LPS).

20. Claims 2-4, 17-18, 21-27, and 45, drawn to a method of treating, preventing or ameliorating chronic **heart failure** or acute heart failure comprising administering **liquorice** or its derivatives, that is able to reduce the production, absorption and/or the effect of an endotoxin (LPS).

21. Claims 2-4, 17-18, 21-27, and 45, drawn to a method of treating, preventing or ameliorating chronic **heart failure** or acute heart failure comprising administering **carbenoxolone** or its derivatives, that is able to reduce the production, absorption and/or the effect of an endotoxin (LPS).

22. Claims 2-4, 17-18, 21-27, and 45, drawn to a method of treating, preventing or ameliorating chronic **heart failure** or acute heart failure comprising administering an **alginate** that is able to reduce the production, absorption and/or the effect of an endotoxin (LPS).

23. Claims 2-4, 17-18, 21-27, and 45 drawn to a method of treating, preventing or ameliorating chronic **heart failure** or acute heart failure comprising administering **sulfacrate** that is able to reduce the production, absorption and/or the effect of an endotoxin (LPS).

24. Claims 2-4, 17-18, 21-27, and 45 drawn to a method of treating, preventing or ameliorating chronic heart failure or acute heart failure comprising administering an **agent that may form a hydrogel** that is able to reduce the production, absorption and/or the effect of an endotoxin (LPS).

25. Claims 2-4, 17-18, 21-23, 25-27, 43 and 45 drawn to a method of treating, preventing or ameliorating chronic heart failure or acute **heart failure** comprising administering a **HMG-coenzyme A-reductase inhbitor** that that is able to increase lipoproteins and is not used to lower LDL/cholesterol level in patient.

26. Claims 2-4, 17-18, 21-23, 25-27, and 45 drawn to a method of treating, preventing or ameliorating chronic **heart failure** or acute heart failure comprising administering a **HMG-coenzyme A-reductase inhbitor** that that is able to increase lipoproteins and is not used to lower LDL/cholesterol level in patient.

27. Claims 54-58, and 69-74, drawn to a method of treating or ameliorating body wasting or **cachexia** in a patient with liver cirrhosis, comprising administering to the patient a compound wherein the compound is **bile acid**.

28. Claims 54-58, and 69-74, drawn to a method of treating or ameliorating chronic **rental failure**, comprising administering to the patient a compound wherein the compound is **bile acid**.

29. Claims 54-58, and 69-74, drawn to a method of treating or ameliorating chronic **diabetes**, comprising administering to the patient a compound wherein the compound is **bile acid**.

30. Claims 54-58, and 69-74, drawn to a method of treating or ameliorating chronic **rheumatoid arthritis**, comprising administering to the patient a compound wherein the compound is **bile acid**.

31. Claims 54-56, 59, and 69-74, drawn to a method of treating or ameliorating body wasting or **cachexia** in a patient with **liver cirrhosis**, comprising administering to the patient a compound wherein the compound is **LPS binding protein**.

32. Claims 54-56, 59, and 69-74, drawn to a method of treating or ameliorating chronic **rental failure**, comprising administering to the patient a compound wherein the compound is **LPS binding protein**.

33. Claims 54-56, and 59, drawn to a method of treating or ameliorating chronic **diabetes**, comprising administering to the patient a compound wherein the compound is **LPS binding protein**.

34. Claims 54-56, 59, and 69-74, drawn to a method of treating or ameliorating chronic **rheumatoid arthritis**, comprising administering to the patient a compound wherein the compound is **LPS binding protein**.

35. Claims 54-56, 60, and 69-74, drawn to a method of treating or ameliorating body wasting or **cachexia** in a patient with liver cirrhosis, comprising administering to the patient a compound wherein the compound is **bacterial/permeability increasing protein (BPI)**.

36. Claims 54-56, 59, and 69-74, drawn to a method of treating or ameliorating chronic **rental failure**, comprising administering to the patient a compound wherein the compound is **bacterial/permeability increasing protein (BPI)**.

37. Claims 54-56, and 59, drawn to a method of treating or ameliorating chronic **diabetes**, comprising administering to the patient a compound wherein the compound is **bacterial/permeability increasing protein (BPI)**.

38. Claims 54-56, 59, and 69-74, drawn to a method of treating or ameliorating chronic **rheumatoid arthritis**, comprising administering to the patient a compound wherein the compound is **bacterial/permeability increasing protein (BPI)**.

39. Claims 54-56, 61, 69-74, and 80, drawn to a method of treating or ameliorating body wasting or **cachexia** in a patient with liver cirrhosis, comprising administering to the patient a compound wherein the compound is **lipoprotein**.

40. Claims 54-56, 61, 69-74, and 80, drawn to a method of treating or ameliorating chronic **rental failure**, comprising administering to the patient a compound wherein the compound is **lipoprotein**.

41. Claims 54-56, 61, 69-74, and 80, drawn to a method of treating or ameliorating chronic **diabetes**, comprising administering to the patient a compound wherein the compound is **lipoprotein**.

42. Claims 54-56, 61, 69-74, and 80, drawn to a method of treating or ameliorating chronic **rheumatoid arthritis**, comprising administering to the patient a compound wherein the compound is **lipoprotein**.

43. Claims 54-56, 62, 69-74, and 80, drawn to a method of treating or ameliorating body wasting or **cachexia** in a patient with liver cirrhosis, comprising administering to the patient a compound wherein the compound is **a combination of LPS binding protein and a lipoprotein.**

44. Claims 54-56, 62, 69-74, and 80, drawn to a method of treating or ameliorating chronic **rental failure**, comprising administering to the patient a compound wherein the compound is **a combination of LPS binding protein and a lipoprotein.**

45. Claims 54-56, 62, 69-74, and 80, drawn to a method of treating or ameliorating chronic **diabetes**, comprising administering to the patient a compound wherein the compound is **a combination of LPS binding protein and a lipoprotein.**

46. Claims 54-56, 62, 69-74, and 80, drawn to a method of treating or ameliorating chronic **rheumatoid arthritis**, comprising administering to the patient a compound wherein the compound is **a combination of LPS binding protein and a lipoprotein.**

47. Claims 54-56, 63, and 69-74, drawn to a method of treating or ameliorating body wasting or **cachexia** in a patient with liver cirrhosis, comprising administering to the patient a compound wherein the compound is **an antibody capable of binding to endotoxin (LPS)**.

48. Claims 54-56, 63, and 69-74, drawn to a method of treating or ameliorating chronic **rental failure**, comprising administering to the patient a compound wherein the compound is **an antibody capable of binding to endotoxin (LPS)**.

49. Claims 54-56, 63, and 69-74, drawn to a method of treating or ameliorating chronic **diabetes**, comprising administering to the patient a compound wherein the compound is **an antibody capable of binding to endotoxin (LPS)**.

50. Claims 54-56, 63, and 69-74, drawn to a method of treating or ameliorating chronic **rheumatoid arthritis**, comprising administering to the patient a compound wherein the compound is **an antibody capable of binding to endotoxin (LPS)**.

51. Claims 54-56, 65, and 69-74, drawn to a method of treating or ameliorating body wasting or **cachexia** in a patient with liver cirrhosis, comprising administering to the patient a compound wherein the compound is **an antibody capable of binding to CD14 receptor**.

52. Claims 53-56, 65, and 69-74, drawn to a method of treating or ameliorating chronic **rental failure**, comprising administering to the patient a compound wherein the compound is **an antibody capable of binding to CD14 receptor**.

53. Claims 54-56, 65, and 69-74, drawn to a method of treating or ameliorating chronic **diabetes**, comprising administering to the patient a compound wherein the compound is **an antibody capable of binding to CD14 receptor**.

54. Claims 54-56, 65, and 69-74, drawn to a method of treating or ameliorating chronic **rheumatoid arthritis**, comprising administering to the patient a compound wherein the compound is **an antibody capable of binding to CD14 receptor**.

55. Claims 54-56, 66, and 69-74, drawn to a method of treating or ameliorating body wasting or **cachexia** in a patient with liver cirrhosis, comprising administering to the patient a compound wherein the compound is a **soluble CD14 receptor**.

56. Claims 54-56, 66, and 69-74, drawn to a method of treating or ameliorating chronic **rental failure**, comprising administering to the patient a compound wherein the compound is a **soluble CD14 receptor**.

57. Claims 54-56, 66, 69-74, drawn to a method of treating or ameliorating chronic **diabetes**, comprising administering to the patient a compound wherein the compound is a **soluble CD14 receptor**.

58. Claims 54-56, and 66, drawn to a method of treating or ameliorating chronic **rheumatoid arthritis**, comprising administering to the patient a compound wherein the compound is a **soluble CD14 receptor**.

59. Claims 54-56, 67, 69-74, and 81, drawn to a method of treating or ameliorating body wasting or **cachexia** in a patient with liver cirrhosis, comprising administering to the patient a compound wherein the compound is a **drug blocking signaling through toll-like receptor**.

60. Claims 54-56, 67, 69-74, and 81, drawn to a method of treating or ameliorating chronic **rental failure**, comprising administering to the patient a compound wherein the compound is a **drug blocking signaling through toll-like receptor**.

61. Claims 54-56, 67, 69-74, and 81, drawn to a method of treating or ameliorating chronic **diabetes**, comprising administering to the patient a compound wherein the compound is a **drug blocking signaling through toll-like receptor**.

62. Claims 54-56, 67, 69-74, and 81, drawn to a method of treating or ameliorating chronic **rheumatoid arthritis**, comprising administering to the patient a compound wherein the compound is a **drug blocking signaling through toll-like receptor**.

63. Claims 54-56, 68, and 69-74, drawn to a method of treating or ameliorating body wasting or **cachexia** in a patient with liver cirrhosis, comprising administering to the patient a compound wherein the compound is a **colostrum**.

64. Claims 54-56, 68, and 69-74, drawn to a method of treating or ameliorating chronic **rental failure**, comprising administering to the patient a compound wherein the compound is a **colostrum**.

65. Claims 54-56, 68, and 69-74, drawn to a method of treating or ameliorating chronic **diabetes**, comprising administering to the patient a compound wherein the compound is **colostrum**.

66. Claims 54-56, 68, and 69-74, drawn to a method of treating or ameliorating chronic **rheumatoid arthritis**, comprising administering to the patient a compound wherein the compound is a **colostrum**.

67. Claim 46 drawn to a pharmaceutical formulation comprising a diuretic and a compound wherein the compound is **bile acid**.

68. Claim 46 drawn to a pharmaceutical formulation comprising a diuretic and a compound wherein the compound is **BI**.

69. Claims 46-47 and 79, drawn to a pharmaceutical formulation comprising a diuretic and a compound wherein the compound is **LPS binding protein**.

70. Claims 46-47 and 78-79, drawn to a pharmaceutical formulation comprising a diuretic and a compound wherein the compound is **lipoprotein or a mixture of lipoprotein**.

71. Claims 46-47 drawn to a pharmaceutical formulation comprising a diuretic and a compound wherein the compound is **an antibody capable of binding LPS**.

72. Claims 46, and 48, drawn to a pharmaceutical formulation comprising a diuretic and a compound wherein the compound is **an antibacterial agent**.

73. Claims 46, and 49 drawn to a pharmaceutical formulation comprising a diuretic and a compound wherein the **compound is able to inhibit the response by a cell to endotoxin**.

74. Claims 46, and 50, drawn to a pharmaceutical formulation comprising a diuretic and a compound wherein the compound is **an agent that is able to reduce the permeability of bacteria and/or endotoxin (LPS)**.

Linking claim 1 will be examined along with Group 1-26 if any one of Groups 1-26 is elected.
Linking claim 53 will be examined along with Groups 1-5, 13-15, and 27-66 if any one of Groups 1-5, 13-15, and 27-66 is elected.
Linking claim 78 will be examined along with Groups 67-74 if any one of Groups 67-74 is elected.

The inventions listed as Groups 1-74 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Daniel *et al* (Circulation 96: 1501-1506, 1997; PTO 892) teach a method of ameliorating chronic heart failure by administering to the patient such as mice an effective amount of a compound such as cardiac glycoside ouabain that is able to reduce the effect of endotoxin (LPS) (See entire document, Effects of Ouabain on LPS-treated mice, in particular). The reference heart failure includes endotoxin-mediated immune activation such as IL-6 and TNFα release (claims 1-2, See Figure 1, in particular).

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have single general inventive concept and lack unity of invention.

Accordingly, Groups 1-74 are not so linked as to form a single general inventive concept and restriction is proper.

IV. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

V. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

VI. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone

are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (703) 872-9306.

VII. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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March 22, 2004

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